

REMARKS

Claims 1-15 and 17-21 are pending herein.

1. Claim 16 has been cancelled without prejudice or disclaimer. All of the rejections thereof are therefore considered moot.

2. Applicant notes withdrawal of Claims 17-21 from consideration by the Examiner and appreciates the Examiner's acknowledgement that should Claims 1-16 become allowable, withdrawn Claim 17-21 will be subject to rejoinder as indicated in the previous Office Action of February 25, 2004.

3. Claim 14 was rejected under 35 U.S.C. §112, second paragraph. Claim 14 has been amended as suggested by the Examiner. Therefore, it is respectfully submitted that Claim 14 is in full compliance of §112. Accordingly, it is respectfully requested that the rejection of Claim 14 under 35 U.S.C. §112, second paragraph, be withdrawn.

4. Claims 1-9 and 10-16 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Additionally, Claims 1-9 and 10-16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement in view of the written description rejection.

Independent Claim 1 been amended to depend from Claim 9, which is directed to SEQ ID NOs: 3-6, and particularly the elected species of SEQ ID NO: 5.

As discussed below, none of the references cited by the Examiner discloses the nucleotide sequences set forth in SEQ ID NOs: 3-6. Therefore, it is respectfully

submitted that Claims 1-9 and 10-15 are in full compliance with §112. Accordingly, it is respectfully requested that the rejections of Claim 1-9 and 10-16 under 35 U.S.C. §112, first paragraph, be withdrawn.

5. Claims 1-16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly based on the disclosure which is not enabling. In particular, the Examiner suggested adding the limitation that the construct includes a nucleic acid sequence encoding insulin or proinsulin operably linked to the construct.

Independent Claim 9 has been amended in the manner suggested by the Examiner. Therefore, it is respectfully submitted that Claims 1-15 are in full compliance with §112. Accordingly, it is respectfully requested that the rejection of Claims 1-16 under 35 U.S.C. §112, first paragraph, be withdrawn.

6. Claims 1-16 were rejected under 35 U.S.C. §102(a) as being anticipated by Thulé et al. (Gene Therapy, 2000, Vol. 7, pp 205-214, hereinafter "the Gene Therapy publication").

It is respectfully submitted that the inventor of the present invention, is the sole inventor of the subject matter relied on by the Examiner in the Gene Therapy publication, to reject Claims 1-16 under 35 U.S.C. §102(a). In this regard, attached hereto is a Declaration of the sole inventor of the present application, Peter M. Thulé, under 37 CFR §1.132. Therefore, it is respectfully submitted that the Gene Therapy publication cannot be used as a *de jure* prior art reference under 35 U.S.C. §102(a). See MPEP §715.01(c). Accordingly, it is respectfully requested that the

rejection of Claims 1-16 under 35 U.S.C. §102(a) over Thulé et al. (the Gene Therapy publication) be withdrawn.

7. Claims 1-16 were rejected under 35 U.S.C. §102(b) as being anticipated by i) Thulé et al. (Diabetes, May 1999, supplement), ii) Thulé et al. (Abstract from Meeting June 9-13, 1999), and iii) Thulé et al. (Abstract from Meeting June, 1998) hereinafter "the Thulé publications").

As noted above, independent Claim 9 is directed to an insulin regulator construct comprising a nucleotide sequence set forth in one of SEQ ID NOs: 3-6, and particularly to the elected species of SEQ ID NO: 5. It is respectfully submitted that none of the Thulé publications cited by the Examiner to reject Claims 1-16 under 35 U.S.C. §102(b) discloses the sequences of Claim 9. Therefore, it is respectfully submitted that Claim 1-15 are not anticipated by any of the Thulé publications. Accordingly, it is respectfully requested that the rejections of Claims 1-16 under 35 U.S.C. §102(b) over the Thulé publications be withdrawn.

INFORMATION DISCLOSURE STATEMENTS

The Examiner is respectfully requested to consider the Information Disclosure Statement filed with this application on October 10, 2001, and return any initialed copy of the Form 1449B/PTO. In that connection, attached herewith is a copy of same, together with a copy of the PCT International Publication No. WO 98/20906. The Examiner is further respectfully requested

to consider the second Supplemental Information Disclosures being filed herewith, and return an initialed copy of the Form 1449B/PTO.


CONCLUSION

In view of the above, it is respectfully submitted that Claims 1-15 are in condition for allowance. Withdrawal of all the rejections and allowance of these claims are earnestly solicited.

It is believed that no additional fee is due for this submission. However, should that determination be incorrect, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'D. Agarwal', written over a horizontal line.

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